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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Edith Dellacherie

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06/11/2010

OLIFF & BERRIDGE, PLC

P.O. BOX 320850

ALEXANDRIA, VA 22320-4850

EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

06/11/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

OfficeAction25944@oliff.com

jarmstrong@oliff.com

Office Action Summary	Application No. 10/522,333	Applicant(s) DELLACHERIE ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-20 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

STATUS OF THE APPLICATION

Applicants' amendments, remarks and Declaration filed 22 February 2010 are acknowledged and entered on the record. The Examiner acknowledges the following:

No claims have been cancelled.

Claims 33 alone has been added. Support for the claims is found in Applicants' specification as well as the previously presented claim 13.

Claims 1, 13, 30 and 32 have been amended. Claims 1 and 32 are amended to include the phrase "extend at least in part". The degree to which Applicants have support for this limitation is unclear and is discussed herein (see **NEW REJECTIONS**). The limitation appears to have been added in an attempt to clarify the claim language already present. As such, the amendments are not considered to add new matter.

Claim 13 is amended to remove the species limitations (e.g. "such as") while claim 30 is amended to correct its dependency.

Thus, claims 1-7, 9-20 and 28-33 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted for consideration.

Art Unit: 1615

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Claims

Applicants' amendment to claim 30 is sufficient in overcoming the improper dependency objection. Thus, said objection has been **withdrawn**.

Rejection under 35 USC 112

Applicants' amendment to claim 13 renders moot the rejection made to claims 13 and 14, under 35 USC 112, second paragraph. Thus, said rejection has been **withdrawn**.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 24 November 2009 since the art which was previously cited continues to read on the amended/newly cited limitations.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1615

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 9-13, 16-20, 28, 29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Illum (USPN 4,904,479).

The independent claims are directed to a particle having a core and a coating, wherein the core comprises at least one biodegradable organosoluble polymer. The coating is comprised of at least one hyaluronan or one of its derivatives. The hyaluronan-based coating is further characterized as either partially or fully encapsulating the particle as well as being chemically modified via ester or amide functional groups so as to form hydrophobic groups which interact with the polymer core (claims 1, 2, 20 and 32). Claim 3 recites that the group which is esterified to hyaluronan is a linear or branched, saturated or unsaturated alkyl chain. Claim 29 further limits the alkyl group of claim 3 such that it is interrupted with one or more hetero atom(s). "Hetero atoms" are defined by Applicants as including sulfur, oxygen and/or nitrogen atoms (see pg. 4, lines 27-29). Claims 9-11 and 28 recite limitations to the biodegradable organosoluble

Art Unit: 1615

polymer, such as polylactic acid, polyglycolic acid and copolymers thereof and that it is a natural biodegradable polymer (claim 28).

The invention of Illum is directed to a drug delivery system comprising an active drug as a suspension of colloidal particles, wherein each particle is coated with a material which provides a hydrophilic coat (claim 1). Though the examples and teachings of Illum are primarily directed to a model where the core particles comprise polystyrene and the coating material comprises poloxamer, it is expressly taught and suggested that other materials may be used to accomplish practiced invention. Of particular note, Illum teaches that the core particles may include polylactides, polyglycolides and mixtures thereof (e.g. copolymers), whereas coating materials which would provide the same effect as the poloxamers include those which may be esterified to produce suitable hydrophilic and hydrophobic domains. It is further suggested that polymers which may undergo such a modification include hyaluronic acid (col. 10, lines 25-41). The hydrophobic domains, which are taught as preferably including polyoxypropylene in addition to other hydrophobic groups can be modified into polymer chains, for example by way of esterification of maleic acid groups (col. 2, lines 31-34). Though maleic acid is an uninterrupted aliphatic dicarboxylic acid compound (e.g. linear alkyl), the continued esterification of multiple maleic acid groups, as suggested by Illum, would result in an aliphatic maleic acid polymer interrupted by oxygen atoms.

Claims 12 and 13 recite that the particle core further comprises at least one biological active, such as proteins. Claim 16 recites that the particle core further comprises up to 95% by weight of an active substance.

Art Unit: 1615

Illum expressly teaches and suggests that the particle core may be alternatively comprised of monomers and copolymers of PLA and/or PGA. It is further taught and suggested that the polymer mixture may also include the protein albumin (col. 10, lines 25-32). Though there is no percentage of albumin which is expressly taught within the core, it is the position of the Examiner that since the protein can be present in the particle core is suggestion enough that it would be present in an amount greater than 0%, which expressly reads on the instant limitation of up to 95% by weight.

Claims 17 and 31 each further limit the composition of claim 1 with regards to its particle size. Claim 17 recites a particle size range of 50 nm (0.05 microns) to 600 microns, whereas claim 31 recites a range of 80 nm to 230 microns. Claim 18 recites that the particle is a nanoparticle, whereas claim 19 recites the particle as a microparticle. Per Applicants' disclosure, a nanoparticle ranges in size from 1-1,000 nm, whereas a microparticle ranges from 1,000 nm to several thousand microns (see pg. 9, lines 8-11).

Illum teaches expressly teaches the instantly claimed nanoparticle sizes (e.g. 50-60 nm) in the Examples (see for example, Example 1, col. 5, lines 20-21). Again though the practiced invention is directed preferably to polystyrene core particles, as discussed above, the polymer core may be substituted with the aforementioned biodegradable polymers. Regarding Applicants' instant claims directed to the larger microparticle ranges, Illum also discusses conducting performing mouse peritoneal macrophage studies where larger microspheres having a 5.25 micron diameter are used (see e.g. col. 3, lines 40-47).

Art Unit: 1615

Thus, in view of the express teachings provided by Illum, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to have arrived at a particle composition as instantly claimed. Though the practiced invention of Illum is directed primarily to polystyrene core particles encapsulated with a polyoxyethylene-polyoxypropylene based coating, the ordinarily skilled artisan would have been highly motivated to derived a composition, for example, of a PLA-PGA copolymer core having an esterified hyaluronic acid coating.

Based on the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, alone or in combination, especially in the absence of evidence to the contrary.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Illum et al. with respect to claims 1-3, as set forth above, and della Valle et al. (USPN 4,851,521) in further view of McMurry (3rd Ed.; 1992).

The limitations of claims 1-3 are discussed above. Claim 4 recites that the hyaluronic acid of claims 1-3 has esterified to it an alkyl chain comprising five or more carbon atoms. Claim 5 further narrows the chain length to 15-20 carbon atoms and further recites that the alkyl group has a degree of esterification of at most 15%. Claim 6 further narrows claim 5 to a length of 18 carbon atoms. Claim 7 further limits the composition of claim 6 to a degree of esterification of less than 7%.

Art Unit: 1615

The teachings of Illum are discussed above. Of particular note is that the practiced invention teaches and suggests the use of esterified hyaluronic acid as a coating composition over core particles composed of homo- or copolymers of PLA and/or PGA. However, Illum does not expressly elaborate on the alkyl groups which are esterified to HA except to suggest that maleic acid groups may be used in the esterification reaction. This deficiency further includes the instantly claimed alkyl chain length and the degree of esterification properties.

The invention of della Valle et al. is directed to the preparation and use of the esters of hyaluronic acid in which all or a portion of which of the carboxylic groups of the acid are esterified (Abstract). The esterified alcohol-based hyaluronic acids are taught as being applicable in the pharmaceutical field as carriers of pharmaceutical active agents and or carrying vehicles (col. 5, lines 1-5). Alcohols of the aliphatic series to be used as esterifying components of the carboxylic groups of HA according to the invention include those with a maximum of 34 carbon atoms, which may be either saturated or unsaturated as well as optionally substituted with various sulfur-based (e.g. mercaptan), nitrogen-based (e.g. amine) or oxygen-based (e.g. hydroxyide) components (col. 5, lines 27-34). The aforementioned alcohols are further taught as optionally being interrupted in the carbon atom chain by heteroatoms such as oxygen, nitrogen and sulfur atoms (col. 5, lines 48-50). Though della Valle does generally discuss the degree of esterification of HA with regards to the aforementioned alcohol components (col. 8, lines 18-26), specific degrees of esterification are not, such as those which are instantly claimed.

However, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have prepared esterified forms of hyaluronic acid as taught by della Valle and applied them as coating compounds to the PLA and/or PGA copolymer core

Art Unit: 1615

particles of Illum. The ordinarily skilled artisan would have been highly motivated to do this particularly in view of the aforementioned teaching of Illum where PLA/PGA cores are coated with esterified forms of HA. Regarding Applicants limitations of creating hydrophobic groups in order to hydrophobically “anchor” the coating to the particle (i.e. control the degree of esterification), della Valle further teaches that the degree of esterification of the carboxylic groups of HA using an alcohol (e.g. stearic alcohol) is dependent on the desired end-use properties, such as control of hydrophilicity and hydrophobicity. It is further taught that increasing or decreasing the degree of esterification of HA will control its solubility in water (col. 8, lines 18-26). Thus, in view of the combined teachings, it is the position of the Examiner that it would have also been well within the purview of the skilled artisan to employ an esterification reaction (e.g. Fischer esterification reaction) in order to arrive at the desired degree of esterification and thus arrive desired number of hydrophobic groups required to anchor the coating to the particle core (see e.g. pp.803-804 of McMurry; 1992). It follows that the reacting HA in this fashion is a result-effective means for optimizing hyaluronic acid that would have been obvious for a person of ordinary skill in the art to employ. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants’ invention.

Based on the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

Art Unit: 1615

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Illum et al. with respect to claims 1, 12 and 13 as set forth above, and Lee et al (USPN 5,753,234).

The limitations to claims 1, 12 and 13 are discussed above. Claim 14 further limits the composition of claim 13 such that the encapsulated active substance is chosen from glucosamine, hyaluronic acid, chondroitin sulfate and mixtures thereof. Claim 15 further limits the “synthetic active substance” limitation of claim 12 reciting that it comprises a synthetic medicinal product such as anti-inflammatory compounds or antibiotics.

The teachings of Illum are discussed above. Again, of particular note are the teachings whereby the particles prepared by Illum comprise a biodegradable core (e.g. PLA and/or PGA homo- and/or copolymers) and wherein the coating applied may be an esterified form of hyaluronic acid (col. 10, lines 25-41). It should also be noted that the size of particles used taught by the Illum reference range from as small as 50 nm to as large as 5.25 microns. The invention of Illum is deficient in so much as there is no express teaching that the active substance within the PLA/PGA core particle is any of those which are instantly claimed. However, the teachings of Lee et al. rectify this deficiency.

Lee et al. is directed to the preparation of microparticles which range in size from 0.5-300 microns and which are prepared by dissolving one or more antigens in an aqueous solution and removing the residual water to form a core particle. Said active core particles are then coated with a biodegradable polymer (Abstract). Exemplary water-soluble substances are taught as including hyaluronic acid (col. 6, lines 2-5). Exemplary antigens are expressly taught as including antibiotics, antiviral agents and immunizing substances (col. 5, lines 46-55).

Art Unit: 1615

Exemplary hydrophobic used to encapsulate the cores include PLGA, PGA and PLA, where PLGA and PLA are preferred (col. 6, lines 30-36). The biodegradable polymer is further taught as being used in an amount which ranges as high as 100-times the individual particle weight (col. 6, lines 23-25). It is thus the position of the Examiner that the particles which are prepared by Lee expressly teach the instantly claimed biodegradable polyester core which further encapsulates one or more of the active ingredients of recited in claims 14-15.

Thus, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have coated the medicated PLA/PGA microparticle prepared by Lee using a hyaluronic acid-based coating composition as taught by Illum in order to produce the instantly claimed composition. The ordinarily skilled artisan, recognizing that the Illum teachings are directed to using an HA-based coating to encapsulate a biodegradable polyester-based core particle, would also recognize that the Lee invention prepares the same type and size of particles which are coated by Illum. The only exception is that the particles prepared by Lee further encapsulate an active substance. Given that both of the references are directed to the formation of pharmaceutical delivery formulations, the ordinarily skilled artisan would be motivated to modify the teachings of Illum with the particle of Lee in order to control the release of the active ingredient.

Thus, based on the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the Illum reference (i.e. primary reference) as it pertains to each of the above rejections under 35 USC 103(a) have been fully considered but they are not persuasive. It is understood that Applicants traverse the initial "Illum" rejection in an effort to overcome each of the rejections as they all depend on Illum.

Concerning the rejections, Applicants allege that the Illum reference is invariably directed to embodiments which adsorb the coating composition to the particle core versus absorbing it to the core as instantly claimed. It is also asserted that the amendment to claims 1 and 32 are sufficient in setting forth this distinction. Lastly, Applicants traverse the rejection stating that the methods employed in arriving at the respective compositions are different, and thus result in the production of structurally distinct compositions (see Remarks and Declaration).

Initially, the Examiner acknowledges the submission of Applicants' Declaration and has thoroughly reviewed and considered it. As it appears to reiterate the points made in the response to the rejection, it will be addressed herein as part of said remarks.

Secondly, in response to Applicants' amendments, the Examiner respectfully submits that the newly added limitation "extend at least in part" does not assist in clearly and distinctly claiming how the coating is associated with the core particle to which it is attached. The limitation "extend at least in part" which is newly amended into both claims 1 and 32 is not defined by the claim, does not appear to be defined by the specification and does not provide a standard for ascertaining the requisite degree to which the molecules extend into the particle. Applicants address in their remarks as well as their Declaration that a key difference between the instant invention and the art of record is that the Illum coating, while anchoring itself to the

Art Unit: 1615

particles as a coating, does not appear to penetrate beneath the surface of the core (e.g., into the core). The addition of the above phrase fails to provide further clarity because it is not clear how far into the polymer core the hydrophobic groups are partially extending. The “extended at least in part” limitation is thus broadly and reasonably interpreted by the Examiner as being read upon by the interaction of (e.g., intertwining of) the functional groups of the coating composition with those of the surface of the core particle. Such an interaction is considered to “extend at least in part” into the particle core and thus read upon by both adsorption and absorption of a coating to a core [*emphases added*].

In response to Applicants’ arguments that the references fail to show certain features of Applicants’ invention, it is noted that the feature upon which Applicants’ argument relies (i.e., the methods for producing the coated particles) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For these reasons, Applicants’ arguments are found unpersuasive. Said rejection is therefore **maintained** and extended to include newly recited claim 33. Claim 33, previously set forth in claim 13 (e.g. independently set forth “such as” limitations), recites that the matrix comprises either glycosaminoglycans or biological factors involved in the process of regeneration and/or protection of cartilage (e.g. chondrocytes). Interpretation of the particle “matrix” relative to the core/coating particle composition is not clearly set forth in the instant disclosure and is thus interpreted broadly and reasonably as addressing both the core and coating. As such the claim is considered as being read upon by the art of record as it already teaches the incorporation of hyaluronic acid (e.g. hyaluronan) in the overall composition.

Art Unit: 1615

ART OF INTEREST CITED

A further brief search of the prior art by the Examiner has resulted in the following document which is also considered to read on and minimally render obvious the instant claims: Vacanti et al. (USPN 5,736,372).

REQUEST FOR REJOINDER

Applicants' request for rejoinder for non-elected claims 8, 19 and 21-24 based on the allowability of the previously elected product claims has been fully reconsidered, but is not persuasive. Since the presently elected claims are not considered to be in condition for allowance, it follows that the non-elected claims remain presently withdrawn from consideration.

All claims have been rejected; no claims are allowed.

CONCLUSION

Applicants' amendments necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

Art Unit: 1615

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615